



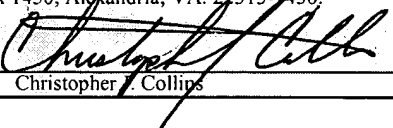
PATENT
Attorney Docket No. **UM-06855**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Kotoku Kurachi *et al.***
Serial No.: **10/018,392** Group No.: **1633**
Filed: **12/06/01** Examiner: **Nguyen, Q.**
Entitled: **Nucleotide Sequences For Gene Regulation and
Methods of Use Thereof**

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450.	
Dated: <u>January 22, 2007</u>	By: <u></u> Christopher Collins

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following patents and publications are referred to in the body of the specification:

- U.S. Patent No. 4,683,195 issued July 28, 1997 to Mullis *et al.*;
- U.S. Patent No. 4,683,202 issued July 28, 1997 to Mullis;
- U.S. Patent No. 4,965,188 issued Oct. 23, 1990 to Mullis *et al.*;
- U.S. Patent No. 5,591,601 issued Jan. 7, 1997 to Wagner *et al.*;
- U.S. Patent No. 5,545,806 issued Aug. 13, 1996 to Lonberg *et al.*;
- U.S. Patent No. 5,569,825 issued Oct. 29, 1996 to Lonberg *et al.*; and
- U.S. Patent No. 5,625,126 issued Apr. 29, 1997 to Lonberg *et al.*
- Saito (1991) "Normal Hemostatic Mechanisms," in *Disorders of Hemostasis*, O.D. Ratnoff and C.D. Forbes, Eds., Saunders, Philadelphia, ed. 2, pp. 18-47;
- Anderson and Young, Quantitative Filter Hybridization, in *Nucleric Acid Hybridization* (1985)¹;

01/25/2007 SSITHIB1 00000079 10018392

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¹ This reference was cited in the application as a general text book without any direction to the page(s) and therefore no excerpts are included in the PTO 1449.

A. Proper Markush Groups Do Not Require Restriction

The Applicants' Markush groups in Claims 5, 8-10, and 16 comport with the standard MPEP guidelines associated with evaluating a Restriction Requirement:

The members of the Markush group ... ordinarily must belong to a recognized physical or chemical **class** or to an art-recognized **class**.

MPEP 803.02: Markush Claims [emphasis added].

1. Claims 5 & 10 Do Not Require A Species Election

In Claims 5 & 10 SEQ ID NOS: 91, and 94-144 meet the “physical/chemical/art-recognized class” requirement. Nucleotide sequences are physically and chemically within the same class, and are recognized by those having ordinary skill in the art as belonging to the same class. The Examiner is incorrect when arguing that nucleic acids of different sequences belong to a different physical and/or chemical class.

Further, the Examiner must realize that these nucleic acid portions all contain significant overlapping segments of identical nucleotide sequence. Consequently, the Applicant's Markush group members comport with the standard guidelines for not requiring a Restriction Requirement:

If the members of the Markush group are ... so closely related that a search and examination of the entire claim can be made without serious burden, the examiner **must** examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions ...

MPEP 803.02: Markush Claims [emphasis added]. These Markush elements meet the “closely related” requirement because they are all nucleic acids having sequences of high homology. The Applicants' point to the underscored sentence above to reiterate that it is not relevant if the Examiner continues to believe that independent and distinct inventions are still present, the pending Restriction Requirement is, by law, unreasonable and must be withdrawn.

The Applicants respectfully request that the Examiner reconsider this species election.

2. Claim 8 Does Not Require A Species Election

In Claim 8, the encoded proteins listed in the properly constructed Markush group meet the “physical/chemical/art-recognized class” requirement. All proteins are physically and chemically within the same class, and are recognized by those having ordinary skill in the art as belonging to the same class (i.e., for example, amino acid

polymers). The Examiner is incorrect when arguing that difference amino acid sequences necessarily belong to a different physical and/or chemical class.

The Applicants respectfully request that the Examiner reconsider this species election.

3. Claim 9 Does Not Require A Species Election

In Claim 8, the encoded proteins listed in the properly constructed Markush group meet the “physical/chemical/art-recognized class” requirement. All recited promoters are physically and chemically within the same class, and are recognized by those having ordinary skill in the art as belonging to the same class (i.e., for example, nucleic acid polymers). The Examiner is incorrect when arguing that different nucleic acid sequences necessarily belong to a different physical and/or chemical class.

The Applicants respectfully request that the Examiner reconsider this species election.

4. Claim 16 Does Not Require A Species Election

In Claim 16, the host cells listed in the properly construction Markush group meet the “physical/chemical/art-recognized class” requirement. All recited host cells are within the same art-recognized class (i.e., for example, living biological cells having the capability of being transfected and subsequently grown in culture). The Examiner is incorrect when arguing that host cells from different species necessarily belong to a different physical and/or chemical class.

The Applicants respectfully request that the Examiner reconsider this species election.

II. Default Election

The Applicants provide an election of the Examiners' offered species elections only because required to do so under 35 U.S.C. § 121. If the Examiner decides not to reconsider the species elections, the Applicants choose:

SEQ ID NO: 144 from Claims 5 & 10;

Factor IX from Claim 8;

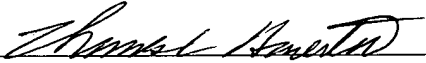
Human Factor IX promoter from Claim 9; and

Mammalian host cell from Claim 16 (and therefore, Claim 15).

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

Date: January 22, 2007


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(37 CFR § 1.98(b))

Applicant: Kotoku Kurachi *et al.*

Filing Date: 12/06/01

Group Art Unit: 1633

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	4,683,195	7/28/97	Mullis <i>et al.</i>	435	6	2/07/86
	2	4,683,202	7/28/97	Mullis	435	91	10/25/85
	3	4,965,188	10/23/90	Mullis <i>et al.</i>	435	6	6/17/87
	4	5,591,601	1/7/97	Wagner <i>et al.</i>	435	69.1	5/14/93
	5	5,545,806	8/13/96	Lonberg <i>et al.</i>	800	2	12/16/92
	6	5,569,825	10/29/96	Lonberg <i>et al.</i>	800	2	12/17/91
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Examiner:

Date Considered:

EXAMINER:

Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: UM-06855	Serial No.: 10/018,392
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicant: Kotoku Kurachi <i>et al.</i>	
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Examiner:			Date Considered:		
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					